

REMARKS

The following amendment is made in response to the Office Action dated January 10, 2007.

In this amendment, claims 3-9, 28-31, 34-36, 45-87 have been cancelled, claims 1, 20, 21, 24, 25, 26, 32, 38, 40 and 41 have been amended, and new claims 88-90 have been added. Thus, claims 1, 2, 10-27, 32, 33, 37-44 and 88-90 are presented for further consideration.

Accompanying this Amendment is an information disclosure statement and 1449.

In the Office Action dated January 10, 2007, the examiner rejected as anticipated claims 1,2, 5-9, 26-28, 34-39, 45, 46, 49-53, 61, 62, 67, 70-74 and 77-79 by Bolelli (US Patent No. 5,855,233) and claims 1,2, 5-9, 24-46, 49-53, 63, and 67-78 by Dworak (US Patent No. 5,549,144). Further, the examiner rejected as obvious claims 3, 4, 47 and 48 over Bolelli and Dworak, claims 10-13 and 54-57 over Bolelli in view of Kincaid (US Patent No. 3,315,713), claims 1-16 and 54-60 over Dworak in view of Kincaid, claims 14-16 and 58-60 over Bolelli, and claims 17-23 and 63-66 over Bolelli in view of Stevie (US Patent No. 5,320,146) or Dworak in view of Stevie.

In light of the claims cancelled in this amendment, only the following rejections require comment: the position that claims 1,2, 26-27, 37-39 are anticipated by Bolelli; the position that claims 1,2, 24-27, 32, 33, and 37-44 are anticipated by Dworak; the assertion that claims 10-13 are obvious over Bolelli in view of Kincaid; the assertion that claims 1, 2, and 10-16 are obvious over Dworak in view of Kincaid, The position that claims 14-16 are obvious over Bolelli, and the position that claims 17-23 are obvious over Bolelli in view of Stevie or Dworak in vie of Stevie.

**Claim 1 are Novel over US 5,855,233 to Bolelli**

Bolelli discloses a method of loading a capsule base with medicament powder. There is no disclosure in Bolelli of the method comprising steps b) – f) of amended claim 1. Amended claim 1 requires *inter alia* that these steps take place *while there is relative rotary motion of the perforated plate and the first director blade*. In contrast, the method in Bolelli involves *intermittently stopping* the rotary body (7) so that the pushers (15-18) can perform their respective compaction and transfer roles (for example, see column 4, line 39-column 5, line 12).

An additional feature that distinguishes Bolelli, includes but is not limited to the fact that the claimed invention requires the step of *closing off one of the perforations in the disk by inserting a blanking pin into the perforation through the second opening*, to the contrary, Bolelli lacks a blanking pin and disclose an closure plate underlying the perforate plate to close the second opening during filling;

The amended claims therefore define a novel method compared to Bolelli.

Furthermore, Bolelli does not render the claimed invention obvious when combined the knowledge of one of ordinary skill. There is no suggestion or motivation to modify Bolelli in order to function in accordance with claim 1. Any suggestion by the Examiner that Bolelli would be adapted to arrive at the claimed method could only be based on an after the fact/hindsight analysis. It is an essential feature of Bolelli to have a "stop-start" methodology. Bolelli thus teaches in a different direction than the claimed method. Therefore, to propose modifying Bolelli to change this essential feature would be ignore the teachings of that reference.

Furthermore, the use of a blanking pin adds flexibility in dosing within the filling device that does not require retooling to change the volume of the perforation in the plate. To modify the dose in Bolelli, one would have to change the volume of powder in the perforate pate, which would likely entail changing the size of the perforation, as well potentially modifying the pushers 15, -17, 18A. Retooling is expensive, in terms of both new manufacturing components as well as in terms of lost productivity due to machine down time.

The claimed invention provides an advantage over Bolelli by allowing a change in volume of the perforation without costly retooling by changing the degree to which a blanking pin extends into the second opening of the perforation. This avoids new machine parts expense, and requires less down time than a retooling process.

Thus, the claimed invention is novel and non-obvious over Bolelli.

**The Pending Claims are Novelty over US 5,549,144 to Dworak**

The claimed method is not anticipated by Dworak. Amended claim 1 requires *inter alia* a first director blade spaced from the first side of the perforated plate and the use of a blanking pin to close off the perforation in the plate for filling of the perforation. In contrast with the claimed subject matter, none of the plows/wipers (84, 86, 88) in Dworak are spaced from the plate (52), therefore they do not constitute a director blade as claimed. If they were, powder would be shown passing under them in Fig 2.

Dworak also differs from the claimed subject matter in that blank is achieved with a blanking plate (60, Fig 1) rather than a blanking pin which extends into the second opening of the perforation.

Lastly, Dworak fails to teach use of a blanking pin and compaction pin operating together.

The amended claims therefore define a novel method relative to Dworak, as the reference fails to meet the limitations of claims 1, let alone dependent claims 2, 24-27, 32, 33, or 37-44.

Furthermore though, Dworak does not render the instantly claimed invention obvious when combined with the knowledge of ordinary skill.

Dworak teaches use of a blanking plate. This is a simple and inexpensive means of blanking the perforated plate for filling of the perforation. The use of a blanking pin in the claimed method is complicated and expensive, considering the need to synchronize the insertion and removal of the pin while there is the relative rotary motion between the plate and the first director blade (yet it provides its own advantages as discussed above in the discussion of Bolelli). Dworak, by using a blanking plate, teaches the person of ordinary skill away from the use of blanking pins.

Moreover, the use of a first director blade in Dworak in place of the plows/wipers (84, 86, 88) would result in the powder not being restricted to its recirculation path (20a, Fig 2), as required for successful operation of Dworak. The skilled person would therefore not modify Dworak to meet the requirements of the claimed method.

For these reasons, the amended claims are non-obvious over Dworak when considered alone.

**Claims 10-13 are Non-obvious over Bolelli in view of Kincaid**

The Bolelli reference describes a container filling apparatus wherein powder positioned in a channel 6 is drawn along the base of the channel by a fixed scraper blade 4 which is substantially in contact with the channel base (col. 2, lines 43-47). Blade 4 guides powder into holes 9 and 9A in the base of the channel. The powder then pass through a series of further holes 10B, 12 and 14 with the assistance of pushers 15, 16, 17 and 18 during the intermittent halting of the apparatus to ultimately fill capsule bases 2 with powder.

As stated above, there is no disclosure in Bolelli of the method comprising steps b) – f) of amended claim 1.

Kincaid is directed to a rotary filling apparatus that avoids the use of intermediate measuring receptacles. In Kincaid employs a rotary plate 17 having disposed through it a number of openings 18. Powder poured on the upper surface of the plate is directed by a series of rakes 76 over the surface of the plate and into the holes 17, under which lie a series of containers 11. Inserted through hole 18 and into the underlying receptacle is a volume occupying probe 57, that is used to control the amount of powder filling the receptacle. Powder directed into the hole, flows therethrough and fills the space in the container not occupied by the probe. The probe is then withdrawn, leaving the powder in the now partially filled container.

The elements of claim 1 and the claims dependent thereon are not found in Kincaid and Bolelli when considered together. For example, neither Kincaid nor Bolelli teach the use of a blanking pin, as claimed, let alone the remaining features in the dependent claims.

As a matter of law, there is insufficient basis for a finding of obviousness when the cited references fail to disclose each and every limitation of the claimed invention. Therefore, any discussion of motivation to combine the references, teachings away, expectation of success and secondary considerations are unnecessary to make.

Allowance of the claims under these circumstances is therefore requested.

**Claims 1, 2, and 10-16 are Non-obvious over Dworak in view of Kincaid**

As mentioned above, Dworak and Kincaid fail to teach each of the elements of the pending claims, i.e., method step b-f of claim 1, when the references are considered alone or in combination. For example, neither teach the closure of the second opening in the disk by use of a blanking pin in the manner claimed in element

b of claim 1. Dworak relies on a blanking plate which does not extend into the second opening in the plate perforations. Kincaid lacks a closing blanking pin.

Also as mentioned above, the examiner will note that this method using a closing blanking pin advantageously allows control of the volume of the perforation to be filled in a manner that differs from the Dworak and Kincaid references, and thus control of the dosage of powder delivered by the method, offering flexibility and cost advantages not found in a blanking plate assembly.

For these reasons, Claims 1, 2, and 10-16 are not obvious over Dworak in view of Kincaid. Withdrawal of the obviousness rejection is therefore requested.

**Claims 14-16 are non-obvious over Bolelli**

Claims 14-16 are indirectly dependent on claim 1. As previously stated, the Bolelli reference does not anticipate claim 1, nor does it render claim 1 obvious. Claims 14-16 are patentable for these same reasons.

In addition, it is asserted that the downward compressive force exerted by the blade on the powder as claimed in claims 14-16 assists in filling the receptacles with the powder as the powder is passed between the blade and the open first side of the perforations. Further, depending on the flow properties of the powder, the positioning of the blade over the powder exerts a disruptive force on the powder residing over the first opening of the perforation. This disruptive force allows the blade configured as in claims 1, 10-16, to potentially overcome the tendency of the powder to "bridge" over the first opening and not flow into the perforation. It is believed that the disrupted powder flows more consistently.

Greater consistency in dosing is highly desired in manufacture, and results in an increase in products meeting product specification, thus reducing the rate of product rejection and decreasing the overall cost of goods. Decrease the overall cost of goods is especially desirable where the product being filled is a medicine which is either expensive or in short supply, or where sales margins are subject to great competitive pressure.

For these reasons, it is asserted that claims 14-16 are non-obvious over the Bolelli.

**Claims 17-23 are non-obvious over Bolelli in view of Stevie or Dworak in view of Stevie**

Claims 17-23 are directly or indirectly dependent on claim 1. As previously stated, neither the Dworak or Bolelli references anticipate claim 1, nor do either of

these references render claim 1 obvious. Claims 17-23 are patentable for the same reasons that claim 1 is patentable.

In addition though, Stevie does not remedy the shortcomings of Dworak or Bolelli. Stevie lacks any blanking pin or compactor pin for that matter, and therefore adds nothing to the discussion of a methodology employing those features.

It will also be noted that Stevie relates to a completely different technique of powder filling—rotational spout filling. Stevie is intended to overcome the problems of cavitation and turbulence in, for example, granular powders that are supposedly experienced in spout fillers when operated at varying speeds.

Neither Dworak or Bolelli relate to spout filling, and there is no indication that cavitation or turbulence effect the volumetric cavity filling approach addressed by those references. Therefore, there is no reason expressed why Bolelli or Dworak would be modified in the manner the examiner proposes.


For these reasons, Claims 17-23 are non-obvious over Bolelli in view of Stevie or Dworak in view of Stevie. Withdrawal of the rejection is respectfully requested.

**Obviousness-type Double Patenting Rejection Is Overcome**

Applicants have enclosed a terminal disclaimer to USSN 10/509,466, thus overcoming the obviousness type-double patenting rejection. This terminal disclaimer is provided to expedite prosecution of the instant claims, and is filed without prejudice. It should not be deemed as acquiescence to the basis for the rejection.

Respectfully submitted:

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